DETAILED ACTION

Status of Claim:

Claims 1-10, 18 and 19 are pending and is subject of this office action. The finality of the office action mailed on 09/30/2900 is hereby withdrawn due to new grounds of rejection set forth below. Claims submitted on 01/30/2009 are now entered and will be examined in the instant office action.

Claim Objections

Claims 7-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102 (e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated in Antoncic et al. (US 7271269).

Antoncic et al. discloses a potassium salt of losartan characterized by a powder X-ray diffraction pattern with peaks at about 2θ 6.9, 13.8, 20.6, 24.8, 28.7, 29.2° (Form X) (column 14, lines 14-17) and pharmaceutical composition containing polymorphic forms of losartan specifically the form exhibiting strongest diffractions at around 2θ 6.9, 13.8, 20.6, 24.8, 28.7, 29.2° (Form X) (column 15, lines 41-42 and lines 63-65). This reads on instant claims 1, 2 and 4.

Antoncic et al. discloses an aspect of their invention where in the pharmaceutical active ingredient of the composition is the amorphous form of losartan (column 17, lines 11-16) (reads on instant claim 3) and film coated tablet formulations of potassium salt of losartan with suitable excipients (column 16, lines 12-21) (reads on instant claim 5). The following examples 52a and 52b disclosed by Antoncic et al. describes the coated tablet formulation of polymorphic forms of potassium salt of losartan. Excipients claimed in the instant claim 1 and 6 are indicated by arrows in the examples.

EXAMPLE 52a

(Film Coated Tablets)
Composition of a tablet

core	
Losartan potassium	100.000 mg
Silicified Microcrystalline Cellulose	198.200 mg
Croscarmellose Sodium	16.000 mg
Silica Colloidalis Anhydrica	3.250 mg
Magnesium stearate	1.600 mg
coating	
Hydroxypropylcellulose	4.960 mg
Ethylcellulose	6.545 mg
Triethyl citrate	2.000 mg
Titanium dioxide	1.088 mg
Ferric oxide red	0.620 mg
Talc	2.000 mg
Weight	336.000 mg
*Ethanol	120.000 mg
"Talc	0.220 mg

*Ethanol is removed during the process
"Talc is not included into the coating polishing agent

EXAMPLE 52b

(Film Coated Tablets)

Composition of a Tablet

core	
Losartan potassium	100.000 mg
Silicified Microcrystalline Cellulose	199.200 mg
Croscarmellose Sodium	16.000 mg
Silica Colloidalis Anhydrus	5.400 mg
Magnesium stearate	1.600 mg
coating	
Hydroxypropylcellulose	10.800 mg
Stearic acid	2.120 mg
Triethyl citrate	0.800 mg
Titanium dioxide	1.080 mg
Ferric oxide red	0.020 mg
Talc	1.170 mg
Weight	336.000 mg
*Ethanol	140.000 mg
"Talc	0.220 mg

*Ethanol is removed during the process
"Talc is not included into coating, polishing agent

Antoncic Example 52a	Weight, mg	Component weight %/ finished dosage form
Losartan potassium	100 mg	29.74
Croscarmellose sodium	16.0 mg	4.76
Finished dosage weight total (plus 0.22 mg of talc)	336.22	
Antoncic example 52b		
Losartan potassium	100.00 mg	29.74
Croscarmellose sodium	16.00 mg	4.76
Stearic acid	2.1 mg	0.6
Finished dosage weight total (plus 0.22 mg of talc)	336.22	

In Antoncic's example 52a and 52b above calculation of % weight of Croscarmellose sodium with reference to the finished dosage weight as shown in the above table yields 4.76% which anticipates the % weight of the stabilizer claimed in instant claims. Calculations of % weight of stearic acid in Antoncic's example 52 b (shown above) yields a value of 0.6% which anticipates the concentration of stearic acid claimed in instant claim 6.

Antoncic discloses that Losartan is used as an effective drug for the treatment of hypertension (col.1, lines 26-29, col.3, line 65 to col. 4, line 1) Antoncic additionally discloses that the pharmaceutical composition of his invention can be in a form suitable for peroral or parental application and is e.g. indicated for treating hypertension (col.16, lines 3-5) in addition to teaching the use of crystalline potassium salt of losartan for manufacturing a medicament for the treatment of hypertension (col. 17, lines 40-42). Accordingly, Antoncic anticipates the instant claims 18 and 19.

Accordingly, instant claims 1-6 and 18-19 are anticipated by Antoncic et al.

Conclusion

Claims 1-6 and 18-19 are rejected. Claims 7-10 are objected

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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